K091159

JUL 10 2009

510(k) Summary

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Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Stacey Bonnell Regulatory Affairs Specialist Telephone: 610-719-5895 Facsimile: 610-719-5102 Email: bonnell.stacey@synthes.com
Date Prepared:	April 17, 2009
Trade Name:	Synthes Oracle Plate System
Classification:	21 CFR 888.3060 – Spinal Intervertebral Body Fixation Orthosis Class II Orthopaedic and Rehabilitation Devices Panel Product Code: KWQ
Predicates:	Synthes Oracle Plate System is substantially equivalent to similar previously cleared predicate devices.
Device Description:	The Synthes Oracle Plate is an addition to Synthes' existing anterior/anterolateral/lateral thoracolumbar spine systems. The Oracle Plate implant consists of a plate and 4 bone screws, all manufactured from Titanium Aluminum Niobium (Ti-6Al-7Nb) ASTM F1295, the same material as the predicates.
Intended Use/ Indications for Use:	The Synthes Oracle Plate is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels, or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or failed previous fusion. Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
Comparison of the device to predicate device(s):	The Synthes Oracle Plate System is a result of design modifications to the predicate devices. It is substantially equivalent to the predicates in design, function, material, and intended use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Bench testing results demonstrate that the Synthes Oracle Plate System is substantially equivalent to the predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes Spine
% Ms. Stacey Bonnell
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

JUL 10 2009

Re: K091159
Trade/Device Name: Synthese Oracle Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervetebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 17, 2009
Received: April 21, 2009

Dear Ms. Bonnell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

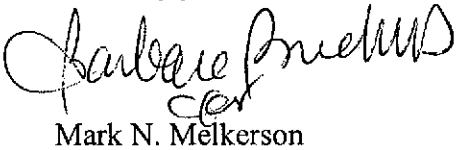
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number: K 091159
(if known)

Device Name: Synthes Oracle Plate

The Synthes Oracle Plate is indicated for use, via the lateral or anterolateral surgical approach above the bifurcation of the great vessels, or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or failed previous fusion.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MKM)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091159

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